BODY PRESCRIPTIONS ANTIBACTERIAL HAND SANITIZER DUO PEPPERMINT SCENTED APPLE SCENTED- alcohol ENCHANTE ACCESSORIES INC.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

50563-294-295-296/BUX0ABS6

BODY PRESCRIPTIONS HAND SANITIZER PEPPERMINT SCENTED

BODY PRESCRIPTIONS HAND SANITIZER PEPPERMINT SCENTED

Active Ingredient

Alcohol 75%

Purpose

Antiseptic

Use

- To decrease bacteria on the skin that could cause disease
- ■Recommended for repeated use

WARNINGS

For external use only. Flammable.

Keep away from heat or flame

When using this product, keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water

Do not use

- in children less than 2 months of age
- on open skin wounds

Stop use and ask a doctor if skin irritation or rash occurs. These may be signs of a serious condition Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away at 1-800-222-1222

Directions

Place enough product on hands to cover all surfaces. Rub hands together until dry. Supervise children under 6 years of age when using this product to avoid swallowing

Other information

Do not store above 105F

May discolor some fabrics

Harmful to wood finishes and plastics

Inactive ingredients

Water, Glycerin, PEG-40 Hydrogenated Castor Oil, Carbomer, Fragrance, Triethanolamine

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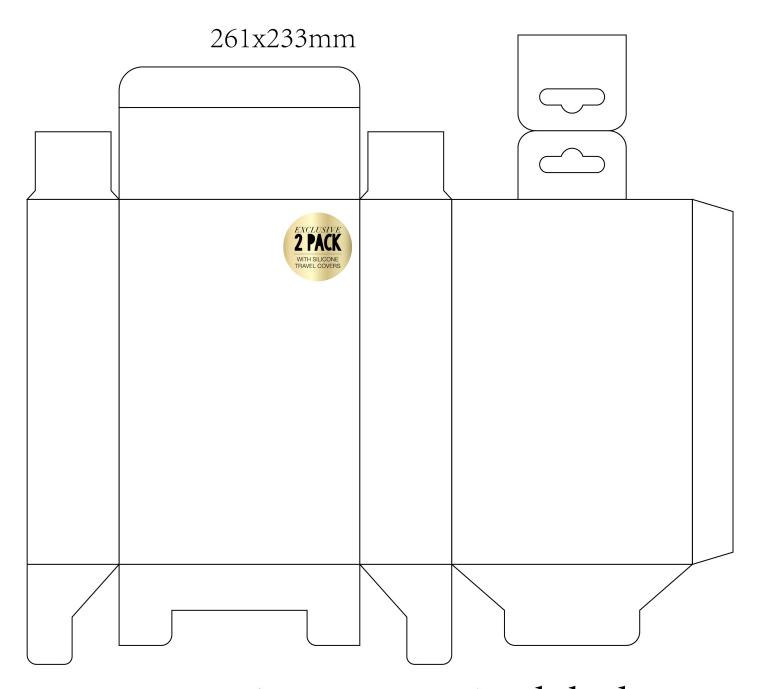
Inactive Ingredients

Water, Glycerin, PEG-40 Hydrogenated Castor Oil, Carbomer, Fragrance, Triethanolamine

10284-7-BUX0ABS6-Back card



FRONT



10284-7 (BUX0ABS6) -label

24*37mm



24*37mm

Drug Facts

Active ingredient Purpose Alcohol 75%......Antiseptic

To decrease bacteria on the skin that could cause disease.
 Recommended for repeated use.

Warnings
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Do not use• in children less than 2 months of age
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first page

24*37mm

Drug Facts (Continued)

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Supervise children under 6 years of age when using this product to avoid swallowing.

second page

24*37mm

Drug Facts (Continued)

Other information

Do not store above 105°F

May discolor some fabrics

Harmful to wood finishes and plastic

Inactive ingredients Water, Glycerin, PEG-40 Hydrogenated Castor Oil, Carbomer, Fragrance, Triethanolamine.

Not tested on animals. For adult use only. Designed in the USA / Made in China Formulated exclusively and distributed by: Enchanté Accessorie Inc., New York, NY 10016 FLOZ (30ML) LOTNO.:BL091420-1 MFG:09/142020 EXP:09/13/2022

third page

24*37mm



24*37mm

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Drug Facts (Continued)

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second page

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Drug Facts (Continued)

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BODY PRESCRIPTIONS ANTIBACTERIAL HAND SANITIZER DUO PEPPERMINT SCENTED APPLE SCENTED

alcohol kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50563-296

	r ackaging			
# Item Code Package Description		Marketing Start Date Marketing End		
1	NDC:50563-296-01	1 in 1 KIT	10/06/2020	

Ouantity of Parts

~		
Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	30 mL
Part 2	1 BOTTLE	30 mL

Part 1 of 2

BODY PRESCRIPTIONS HAND SANITIZER PEPPERMINT SCENTED

alcohol solution

Product Information

NDC:50563-294 Item Code (Source)

Route of Administration TOPICAL

Active Ingredient/Active Moiety

1	ingredient Name	basis of Strength	Strength
ı	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

inactive ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
GLYCERIN (UNII: PDC6A3C0OX)		
CARBOMER 940 (UNII: 4Q93RCW27E)		
TROLAMINE (UNII: 903K93S3TK)		

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:50563-294- 01	30 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Inform	Iarketing Information		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/06/2020	

Part 2 of 2

BODY PRESCRIPTIONS HAND SANITIZER APPLE SCENTED

alcohol solution

Product Information	
Item Code (Source)	NDC:50563-295
Route of Administration	TOPICAL

l	Active Ingredient/Active Moiety		
l	Ingredient Name	Basis of Strength	Strength
l	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
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GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
TROLAMINE (UNII: 903K93S3TK)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	

	Packaging				
:	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	NDC:50563-295- 01	30 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package			

Marketing Information					
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OTC monograph not final	part333A	10/06/2020			
Marketing Inform	Marketing Information				
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OTC monograph not final	part333A	10/06/2020			

Labeler - ENCHANTE ACCESSORIES INC. (186050696)

Establishment			
Name	Address	ID/FEI	Business Operations
Xiamen Afgamarine Biotechnology Co., Ltd.		420485152	manufacture(50563-296)

Revised: 10/2020 ENCHANTE ACCESSORIES INC.